NOVACHECK COVID-19 FAST ANTIGEN TEST

By

EASY TO USE
QUICK RESULT
HIGH ACCURACY

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TÜRKİYE'NİN İLK VE TEK ŞEKER ÖLÇÜM SİSTEMLERİ ÜRETİCİSİNDEN

COVID-19 FAST ANTIGEN TEST

novatech DIAGNOSTICS®

SARS-CoV-2 FAST ANTIGEN TEST

SARS-CoV-2 is an enveloped β-coronavirus with a circular or elliptical particle diameter of about 60 ~ 140 nm, usually pleomorphic, clearly different in genetic characteristics from SARS-CoV and MERS-CoV. Main clinical signs include dry cough with fever, fatigue and other systemic symptoms, shortness of breath and severe life-threatening pneumonia, respiratory failure, acute respiratory distress syndrome, septic shock, multi-organ failure, severe acid-base metabolism disorder. -2 was defined as the main route of transmission through respiratory droplets (sneezing, coughing, etc.) and contact (pulling the nostril with the hand in contact with the virus, rubbing the eyes, etc.).

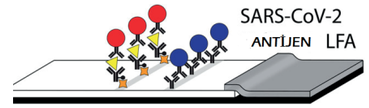
As Novatech medical device products Inc., it has successfully produced the COVID-19 antigen lateral flow test that can detect the presence of COVID-19 in less than 15 minutes. This test offers faster and more effective combat opportunities with the Covid-19 pandemic than existing covid-10 tests offer. The rapid antigen test, which is low-cost and portable, is an effective method to help reduce the spread of the Covid-19 outbreak by detecting individuals with disabilities before symptoms develop.

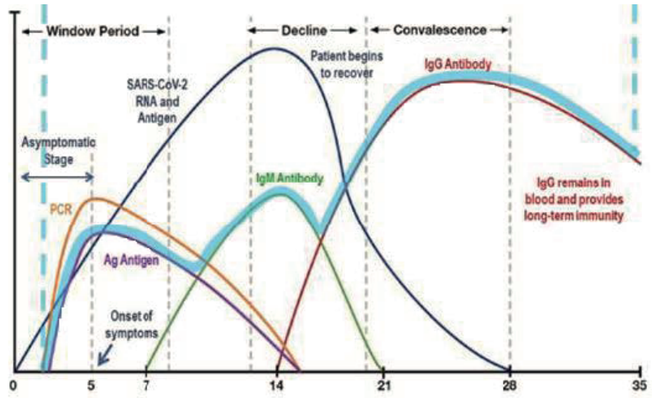
Special handling equipment does not require

Does not require a cold chain

No device required

The SARS-CoV-2 Antigen Rapid Test uses immuno-lateral chromatography technology for the qualitative detection of antigens. Colloidal gold particles binding with anti-SARS-CoV-2 antibody 1 are fixed on the conjugation pad. Anti-SARS-CoV-2 antibody 2 is attached to the "T" test line of the nitrocellulose membrane. Goat (goat) Anti-Mouse IgG is linked to the "C" control line of the nitrocellulose membrane.





The days since the infection Table-1

Figure 1: Variation of the Levels of SARS-CoV-2 RNA and Antigen, IgM and IgG after infection.

When the concentration of "SARS-CoV-2" in the sample is higher than the minimum detection limit, it forms a complex with "Anti-SARS-CoV-2 antibody 1" labeled with colloidal gold particles. This first complex will proceed to the test line by capillary action on the membrane and will be captured by the "Anti-SARS CoV-2 Antibody 2" previously attached to the test line and the "Au-Anti-SARS-CoV-2 Antibody! SARS-COV-2) -Anti-Sars-CoV-2 antibody will form the 2 " complex. These complexes accumulate in the test line, forming a color that allows antigen-positive detection. The remainder of "Anti-SARS-CoV-2 Antibody 1" labeled with colloidal gold particles reveals color conjugated with goat-Anti Mouse IgG in the C control line. If the concentration of "SARS-CoV-2" in the sample is below the minimum detection limit, the complexes produce color only in the C control line.

INTERPRETATION OF TEST RESULTS

A red line appears in the **NEGATIVE** "C" control line region. No lines appear in the "T" test line regions. A negative result indicates that the SARS-CoV-2 antigen content in the sample is below the detection limit or there is no antigen.

A red line appears in the **POSITIVE** "C" control line region and a red line in the "T" test line region. The positive result indicates that the SARS-CoV-2 antigen content in the sample is higher than the detection limit.

When the red line in the **INVALID** "C" control line region does not appear, it will be considered invalid. An invalid result indicates that the procedure is not correct or the test device is outdated or invalid. In this case, the package insert should be carefully read and the test repeated with a new test device.

SARS-CoV-2 Antigen Rapid Test
Clinical report summary

Comparative analysis of test clinical diagnosis results with test reagent results. The detection results of the test reagent and clinical diagnosis results are shown in the following table.

		Clinical diagnostic results		Total
		Confirmed diagnosis	Exclusion	
Test reagent results	Positive (+)	45	0	45
	Negative (-)	3	240	243
Total number		48	240	288

Sensitivity: 93.75%;(%95 CI:83.16%~97.85%)
Specificity: %100;(95% CI:98.42%~100%)
Total clinical coincidence rate: %98.(95% CI: 96.98%~99.65%)

PCR test sonuçları ile test reaktif sonuçlarının karşılaştırmalı analizi
Test reaktifi ve PCR test sonuçlarının tespit sonuçları aşağıdaki tabloda gösterilmiştir.

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Total clinical coincidence rate: %98.96 (95% CI:96.98%~99.65%)

T o yukarıdaki sonuçlar, algılama reaktifi ve PCR sonuçları arasında istatiksel olarak anlamlı bir fark olmadığını gösterdi.

Analysis of standard swab tests is currently

* Costly equipment,
*Highly trained staff requires and should usually be performed in large hospitals or well-equipped PCR laboratories. Also, tests done in this way can take a few hours or days to produce results, which weakens rapid clinical responses. To overcome this, with the use of a portable lateral flow reader, fast, repeatable and high precision results can be achieved without the need for highly trained personnel and complexity.

As a result, we open up the possibility of directing patients into quarantine earlier for better clinical decision making and reducing the spread of disease. The COVID-19 antigen test kit continues to work with full force to optimize function, further improve detection of viral particle lower limit and get accurate results for targeted populations and environments.